

CANCER – Cost Studies**COMPARING FORECASTED WITH ACTUAL BUDGET IMPACT: REIMBURSED CANCER DRUGS IN THE NETHERLANDS**Thuresson PO¹, Heeg B¹, Botteman M²¹Pharmerit, Rotterdam, The Netherlands; ²Pharmerit North America, LLC, Bethesda, MD, USA

OBJECTIVES: In the The Netherlands, a new drug is priced to the level of an existing drug cluster, if these are considered similar. However, when a drug is not considered similar to a cluster, a separate price can be requested. Before this separate price is approved, sufficient cost-effectiveness and budget impact (BI) data have to be provided to the Dutch Health Care Insurance Board (CVZ). The present analysis investigated how close the submitted BI-forecasts were to the actual BIs for cancer treatments in the The Netherlands. **METHODS:** The publicly available evaluations by the CVZ were assessed for cancer agents. From these, forecasted number of users, drug costs, treatment lengths, and the BIs were derived. The predicted BIs were compared with actual BIs from the GIP database (Dutch Drug Information System). The predicted BI was standardized with respect to time to ensure that actual and forecasted BIs shared the same starting point. Broadening of the indication was taken into account and substitution was considered. To further explain any difference in forecasted and actual BI, various variables such as drug cost, number of users, market share (when applicable), and treatment lengths were investigated. **RESULTS:** The search provided five relevant cases. The forecasted budgets were lower than the actual ones in four out of the five cases. The forecasted and actual BI differed up to 250%. Data on drug substitution was insufficient and therefore not considered. The differences between predicted and observed BIs were explained primarily by an underestimation of the number of patients eventually receiving the evaluated treatments. The published BI forecasts contained no/very limited sensitivity analyses. **CONCLUSIONS:** Most BI forecasts underestimated the actual BI for new cancer drugs. One explanation was that the growth of the patient population was often underestimated. Improvements in predicting total market size and penetration should be considered, as well as more elaborate sensitivity analysis.

PCN32**IMPACT BUDGETING IN CROATIA: FULVESTRANT EXAMPLE**Culig J¹, Leppe M¹, Reic P², Serdar S², Boskovic J³, Colak N⁴¹Andrija Stampar Institute of Public Health, Zagreb, Croatia; ²AstraZeneca d.o.o, Zagreb, Croatia; ³University of Zagreb, Zagreb, Croatia; ⁴Colpharm d.o.o, Siroki Brijeg, Bosnia

OBJECTIVES: Chemotherapy is standard choice as third-line treatment in patients with hormone-dependent metastatic breast cancer. The field research has shown that there is a need for additional hormonal drug in order to delay expensive and harmful chemotherapy. The aim is to analyze the impact on the budget Croatian Health Insurance Institute (CHI) budget including the drug fulvestrant 250 mg on the basic drug list as a third-line treatment in patients with hormone-dependent metastatic breast cancer. **METHODS:** Markov model was used to develop a new treatment scenario. Program to calculate the financial impact on the budget was developed in Microsoft Excel. **RESULTS:** The scenario with fulvestrant given as a third line of treatment in a period of 4 months, followed by 4 months of paclitaxel, 3 months capecitabine, and, finally, 4 months with only supportive care was designed. This would delay the application of chemotherapy for an average of 4 months. Therefore, significantly fewer patients will be treated with chemotherapy. Additionally to that, a small part of patients would receive chemotherapy over a shorter period. The quality of life of metastatic breast cancer patients during their life expectancy would be significantly better, with the same expected survival rate and potentially lower cost of treatment. The impact budget analysis has shown reduce of therapy cost (4,202,922 Croatian Kuna or €579,713). **CONCLUSIONS:** A need for additional line of hormonal drug as a third-line treatment that can delay the implementation of poorly tolerated and expensive chemotherapy was established. The effectiveness of fulvestrant qualified it as a good candidate after the failure of the current endocrine therapy. The economic evaluation using Markov models and analysis of the budget impact in Croatia has been proven that adding fulvestrant in sequential treatment of metastatic breast cancer HR+ patients is cost-effective as third-line hormonal therapy in advanced breast cancer.

PCN33**BUDGET IMPACT ANALYSIS OF CAPECITABINE IN ADJUVANT TREATMENT OF PATIENTS WITH RESECTED DUKES' C COLON CANCER (CC) FROM POLISH PUBLIC PAYER'S AND PATIENT'S PERSPECTIVES**Oleszko R¹, Kawalec P², Drobnick A³, Stec R⁴, Streb J⁵, Russel-Szymczyk M⁶, Szkuteczka-Debek M⁶¹Centrum HTA, Kraków, Poland; ²Jagiellonian University, Kraków, Poland; ³Holycross Cancer Center, Kielce, Poland; ⁴Military Institute of Medicine, Warsaw, Poland; ⁵The University Hospital in Krakow, Krakow, Poland; ⁶Roche Polska Sp. z o.o., Warsaw, Poland

OBJECTIVES: The aim of the analysis is to determine budget impact of reimbursement of capecitabine monotherapy used in the adjuvant therapy of patients after resection of stage III CC (Dukes' C). **METHODS:** Cost data were collected from Polish public payer's (National Health Fund) and patient's perspectives and calculated for a 3-year time horizon. The population was estimated based on the Polish National Cancer Register. The following direct medical costs were included: cost of drugs used in

adjuvant, I and II line chemotherapy, drug administration costs, adverse events, and monitoring costs. In "scenario A," capecitabine was not reimbursed by the public payer, while the "scenario B" was developed under assumption of 100% capecitabine reimbursement. The proportion of patients treated with capecitabine and other drugs used in CC treatment was assessed based on the results of a questionnaire study conducted among Polish clinical experts. a cohort Markov model was used for simulation of long-term health outcomes and costs. a range of variables was tested in one- and multi-way sensitivity analyses. **RESULTS:** "Scenario B" introduction led to savings equal to 24,730,000 PLN in the first year, 25,379,000 PLN in the second year, and 26,712,000 PLN in the third year from public payer's perspective (1 EURO = 4.1 PLN). Similarly, savings were observed when patient's perspective was assumed. Results of sensitivity analysis confirmed conclusions from base-case analysis. **CONCLUSIONS:** One hundred percent reimbursement of capecitabine used in adjuvant therapy of patients after the resection for Dukes' C CC leads to savings from both a public payer's and patient's perspectives in Poland.

PCN35**CLINICAL AND ECONOMIC IMPLICATIONS OF SCREENING FOR KRAS MUTATIONS IN METASTATIC COLORECTAL CANCER PATIENTS IN SPAIN: A COST-EFFECTIVENESS AND BUDGET IMPACT MODEL**

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OBJECTIVES: Colorectal cancer is the second most common cancer in Spain (25,600 incident cases and over 13,500 deaths yearly). Mutations in the KRAS oncogene are associated with a poor response to epidermal growth factor receptor (EGFR) inhibitor therapy in metastatic colorectal cancer (mCRC). In addition to avoiding unnecessary toxicity, implementing routine KRAS screening and limiting the use of EGFR inhibitors to patients with wild-type KRAS may lead to cost savings. The objective is to estimate health and economic outcomes derived from carrying out KRAS determination in mCRC patients requiring an aggressive treatment in Spain. **METHODS:** Cost-effectiveness and budget impact analyses from national, regional, and hospital perspectives were developed in an interactive mode. Information was obtained from literature review of clinical trials (treatment response rates and prevalence of KRAS mutations), official statistics (epidemiological data), and local databases (therapy and KRAS test costs). Multivariate sensitivity analysis can be performed by changing the technology for KRAS testing (PCR, real-time PCR), the chemotherapy regime (FOLFIRI, FOLFOX-4), and the proportion of wild-type patients to be treated with each therapy (bevacizumab, cetuximab). **RESULTS:** About 7000 mCRC patients will require an aggressive treatment in Spain in 2010. a strategy based on treating wild-type patients with cetuximab would raise first-line response rate from 44.80% to 53.84% (20.18%, 633 patients more) when combined with FOLFIRI (19.05%, 620 patients with FOLFOX-4) with an additional cost estimate of €22,117 per response (€17,201 with FOLFOX-4). Budget impact of this approach amounts to a 9.06% (5.01% with FOLFOX-4) increase in resources devoted to mCRC treatment. Univariate and multivariate sensitivity analyses yield ratios between €19,101 and €27,531 and budget impact estimates of 0.16–9.16%. **CONCLUSIONS:** Treating wild-type KRAS mCRC patients with cetuximab would lead to over 600 additional patients (19–20%) with first-line response every year in Spain, with an associated budget impact of 9–11% of therapy cost.

PCN36**COST IMPLICATIONS OF RESTRICTING PALONOSETRON UTILIZATION FOR THE TREATMENT OF CINV: RESULTS FROM AN ANALYTIC MODEL FROM A PAYER PERSPECTIVE**Powers A¹, Sarnes E², Knott RL¹, Balu S¹, Buchner D¹¹Eisai, Inc., Woodcliff Lake, NJ, USA; ²Xcenda, Palm Harbor, FL, USA

OBJECTIVES: Palonosetron is a 5-HT₃ receptor antagonist (5-HT₃-RA) indicated for the prevention and treatment of chemotherapy induced nausea and vomiting (CINV). Using an analytic model, this study explored the consequences of the restricted use of palonosetron for the treatment of CINV from a payer perspective. **METHODS:** The analytic model utilized rates of uncontrolled CINV among patients with cancer and initiated on palonosetron or another 5-HT₃-RA for antiemetic prophylaxis. Other inputs included direct medical cost of a CINV event defined by inpatient and outpatient visits, fixed Medicare reimbursement fees for medications (average sale price + 6%), national prescription utilization data, and the costs associated with executing a prior authorization. Total costs associated with restricting palonosetron usage by 10% with a corresponding 10% increase in generic 5-HT₃-RA utilization were modeled for six cycles of moderately (MEC) and highly emetogenic chemotherapy (HEC). **RESULTS:** In a 1 million member health plan, 15,000 patients (1.5%) were estimated to require chemotherapy treatment annually. Of these, 10,800 patients (72%) were estimated to receive 5-HT₃-RA prophylaxis on the first day of chemotherapy, with 7587 (51%) on either a MEC or HEC regimen. Result of the model demonstrated that a 10% reduction in palonosetron led to an overall savings in antiemetic costs equivalent to \$762,616. However, total direct medical costs to the health plan (including the cost to treat uncontrolled CINV and the cost of the prior authorization program) increased by an estimated \$865,457. Total cost of care, therefore, increased by an estimated \$0.02 PMPM. **CONCLUSIONS:** Results from an analytic model showed that restricting palonosetron utilization by 10% through a prior authorization, while decreasing medication costs, produced an overall increase in total direct costs to the MCO. These results suggest that further studies on the clinical and economic impact of appropriate utilization of antiemetic prophylaxis for CINV are warranted.

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